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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,813	04/13/2007	**Ulrich Bogdahn**	JCLA21512	6647

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
11/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,813	BOGDAHN ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed October 28, 2008. This Office Action is also a response to Applicant's Election filed October 28, 2008.

Claims 13-18 and 26-39 have been canceled.

Claims 19-21 have been amended.

Claims 19-25 are pending in the instant application.

Election/Restrictions

Applicant's election, without traverse, of Group III and the further election of SEQ ID NO:1 in the reply filed on October 28, 2008 is acknowledged.

The restriction requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 19-25 have been examined on the merits.

Information Disclosure Statement

It is noted that Applicants have not filed an information disclosure statement under § 1.97(c). Applicant is reminded of 37 CFR § 1.56, which details Applicants duty to disclose all information known to be material to patentability.

Priority

The reference to priority in the first line of the specification is acknowledged. It is noted that the instant application is the national stage entry of PCT/EP05/01298. It is

also noted that certified copies of the priority document have been received in this national stage application.

Drawings

The Drawings filed August 8, 2006 are acknowledged and have been accepted by the Examiner.

Nucleotide Sequence Disclosures

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §1.821-1.825 for the reason(s) set forth below. The disclosure contains sequences which fall under the purview of 37 CFR 1.821 through 1.825 as requiring SEQ ID NOs., but which are not so identified. For example, see pages 13, 17, and 36. The above are examples and are not intended to indicate that the Examiner has made an exhaustive review of the application. Applicant must fully comply with the sequence rules for any response to this action to be considered fully responsive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19-25 are indefinite because the term "TGF-R_{II}" is not clearly defined. Since abbreviations often have more than one meaning, it is suggested that inserting the full name of the growth factor would overcome the instant rejection.

Additionally, claims 19-25 provides for the use of at least one oligonucleotide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-25 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-25 are rejected under 35 USC 102(b) as being anticipated by WO 03/000656 A2.

Claim 19 is drawn to the use of at least one oligonucleotide having a sequence at least 80% identical to a sub-sequence of SEQ ID NO:1 comprising 8 to 50 nucleobases, wherein said sequence is capable of hybridizing sufficiently with the region encompassing the translation initiation or termination codon of the open reading frame of the gene encoding TGF-R_{II} or a region of the mRNA encoding TGF-R_{II} which is a "loop" or "bulge" and which is not part of a secondary structure and mimetics, variants, salts and optical isomers of said sequence for promoting successful regeneration and functional reconnection of damaged neural pathways. Claims 20-25 are dependent on claim 19 and include all the limitations of claim 19 with the further limitations of the use of at least one oligonucleotide as well as mimetics and variants thereof and/or at least one antisense compound comprising a vector allowing to transcribe at least one said oligonucleotide or a pharmaceutical formulation comprising at least one oligonucleotide according to claim 19 for promoting successful regeneration and functional reconnection of damaged neural pathways; the use of at least one oligonucleotide as mimetics and variants thereof and/or at least one antisense compound comprising a vector allowing to

transcribe at least one said oligonucleotide or a pharmaceutical formulation comprising at least one oligonucleotide for prophylaxis, therapeutic prevention and treatment of neurodegenerative, traumatic/posttraumatic, vascular/hypoxic, neuroinflammatory and post infections central nervous system disorders, as well as age induced decrease in neuronal stem cell renewal; the use of at least one oligonucleotide for inhibiting TGF-R_{II} expression in diseases associated with up-regulated or enhanced TGF-R_{II} levels; wherein the diseases associated with up-regulated or enhanced TGF-R_{II} levels or the neurodegenerative disorders and neuroinflammaotry disorders are selected from CNS autoimmune disorders, viral meningoencephalitis, or arteriosclerosis, for example; and the use for inhibiting TGF-β activity in diseases associated with up-regulated or enhanced signaling of TGF-R_{II}.

WO 03/000656 A2 discloses and claims TGF-R_{II} antisense oligonucleotides (see pages 88-90, Table 1, and claims 1 and 2, for example). It is noted that the TGF-R_{II} antisense oligonucleotides comprise a pharmaceutically acceptable carrier (see claims 12 and 14). It is also noted that the oligonucleotide indicated as SEQ ID NO:20 disclosed by WO 03/000656 A2 is 100% identical over the entire length to SEQ ID NO:33 of Applicant's invention. Moreover, some other oligonucleotides disclosed in Table 1 of WO 03/000656 A2 (referred to as "D18" below) overlap with some of the oligonucleotides claimed in Applicant's invention. For example:

D18 oligonucleotides	overlap with	present application's oligonucleotides
SEQ ID NO:20		SEQ ID NOs:3, 29-32, 34-72
SEQ ID NO:48		SEQ ID NOs:3, 29-72
SEQ ID NO:22		SEQ ID NO:27
SEQ ID NO:26, SEQ ID NO:27		SEQ ID NO:28
SEQ ID NO:28		SEQ ID NO:23, SEQ ID NO:5
SEQ ID NO:53		SEQ ID NO:16
SEQ ID NO:55		SEQ ID NO:21
SEQ ID NO:57		SEQ ID NO:17, SEQ ID NO:22
SEQ ID NO:58		SEQ ID NO:18
SEQ ID NO:65, SEQ ID NO:66		SEQ ID NO:26

WO 03/000656 A2 discloses that the antisense oligonucleotides of their invention are used in methods to treat diseases and conditions associated with the up-regulated expression of TGF-R_{II}, said diseases and conditions being, for example, a disease or condition involving activation of the immune system or atherosclerosis (see claims 15, 17 and 20). Therefore, absent evidence to the contrary, WO 03/000656 A2 anticipates claims 19-25.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

November 3, 2008
/Terra Cotta Gibbs/